Remarks

Upon entry of the amendment, claims 41-55, 57-84, 87-93, 136-177 will be pending in the instant application.

Claims 56, 85, 86, 94-135 have been canceled without prejudice or disclaimer. Applicants hereby reserve the right to pursue the subject matter encompassed within said claims in a continuing application. The claim amendments indicated above were made solely to facilitate prosecution and to more particularly point out and distinctly claim the subject matter therein.

Applicants respectfully submit that, as requested by the Examiner in a telephone interview conducted on March 1, 2001, support for embodiments (b) and (c) in claims 136 and 148 is found on page 29, line 10; page 38, line 29; page 40, line 3; page 22, lines 28-33; and Example 19 on page 201.

No new matter has been added by way of this amendment. Entry of the amendment and remarks is respectfully requested.

Rejections Under 35 U.S.C. § 101 and § 112

The Examiner rejects claims 41-177 under 35 U.S.C. §§ 101 and 112, first paragraph in Paper No. 15 because the claimed invention allegedly is not supported by either a specific and substantial asserted utility or a well established utility.

Applicants note that as to claims 136 and 148, particularly embodiment (c), the post-filing data LaFleur et al., offered in Applicants' response filed on January 23, 2002 shows that the claimed protein also demonstrates the ability to activate the Jak/Stat pathway via activation of the ISRE (*see* page 39769, second column and page 39771, first column, first full paragraph of LaFleur et al.). This data corroborates what is taught in the specification on page 191 and on page 201:

> One signal transduction pathway involved in the differentiation and proliferation of cells is called the *Jaks-STATs pathway. Activated proteins in the Jaks-STATs pathway bind to gamma activation site "GAS" elements or interferon-sensitive responsive element ("ISRE")*, located in the promoter of many genes. The binding of a protein to these elements alter the expression of the associated gene.
>
> The type I Interferons are known to signal through a common receptor complex, *activate the Jak/STAT signalling pathway*, and ultimately activate transcription of interferon inducible genes. *Upstream of these type I Interferon Inducible genes is an element known as the ISRE* (Interferon Stimulated Response Element). To determine if KDI can also signal and activate the ISRE element, reporter genes containing an ISRE element (e.g., ISRE-SEAP or ISRE-CAT), are introduced transiently into a type I responsive interferon

cell line. These transfected cell lines are then treated with KD1 (supernatants, recombinant protein, transfected cells or membranes therefrom) and activation of the reporter gene is monitored. (Emphasis added).

Therefore, Applicants respectfully submit that embodiment (c) of claims 136 and 148 is not only fully supported, but is corroborated by LaFleur et al. and therefore satisfies the utility requirement under 35 U.S.C. §101.

Per the Examiner's telephone interview, conducted with Applicants' counsel on March 1, 2002, the utility rejection would be withdrawn in view of Applicants' response and post-filing data filed on January 23, 2002. Applicants thank the Examiner for the withdrawal of this rejection and respectfully request written confirmation of the same.

Rejections Under 35 U.S.C. § 112, first paragraph

A. The Examiner further rejects claims 53, 64, 80, 94, 106, 117, 136, 148, 160, and 169 under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement in their full scope.

Preliminarily, Applicants note that claims 94, 106 and 117 have been canceled without prejudice or disclaimer, thereby rendering this rejection moot with respect to these claims.

Further, solely to facilitate prosecution, Applicants have amended claims 53, 64, 80, 160 and 169 to more particularly point out and distinctly claim the subject matter therein. As a result, Applicants respectfully submit that this rejection has been obviated by said amendments

With respect to the rejection of claims 136 and 148, Applicants respectfully disagree and traverse for the reasons articulated above in the utility discussion and on page 6 of Applicants' response filed January 23, 2002. Applicants respectfully submit that these claims are fully enabled by the present specification as screening assays are taught for detecting anti-viral activity (*see* Example 56 on page 247); inhibition of bone marrow proliferation activity (*see* Example 57 on page 248); Jak/Stat activation (*see* Example 13, page 191; Example 19-21, page 201); and specific antibody binding (*see* Example 11, page 187) for the fragments taught and were well-known to those of skill in the art at the time the invention was filed. Therefore, Applicants respectfully submit that these claims are fully enabled by the specification and respectfully request reconsideration and withdrawal of this rejection with respect to claims 136 and 148.

B. The Examiner also rejects claims 53-135, and 148-177 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Preliminarily, Applicants note that claims 94, 106 and 117 have been canceled without prejudice or disclaimer, thereby rendering this rejection moot with respect to these claims.

Further, solely to facilitate prosecution, Applicants have amended claims 53, 64, 80, 157, 160, 166, 169 and 175 to more particularly point out and distinctly claim the subject matter therein. As a result, Applicants respectfully submit that this rejection has been obviated by said amendments.

With respect to rejected claim 148, Applicants respectfully disagree and traverse. As requested by the Examiner in a telephone interview conducted on March 1, 2001, support for embodiments (b) and (c) in claim 148 is found on page 29, line 10; page 38, line 29; page 40, line 3; page 22, lines 28-33; and Example 13 on page 191; Examples 19-21 on page 201. Further, Applicants respectfully submit that the subject matter encompassed within claims 136 and 148 was clearly contemplated by Applicants as the present specification teaches screening assays for detecting anti-viral activity (*see* Example 56 on page 247); inhibition of bone marrow proliferation activity (*see* Example 57 on page 248); Jak/Stat activation (*see* Example 13, page 191; Example 19-21, page 201); and specific antibody binding (*see* Example 11, page 187) for the fragments taught. In this way, the common feature required of all members of the fragments claimed in claim 148 are recited in the activities claimed and therefore clearly contemplated by Applicants. Therefore, Applicants respectfully submit that claim 148 satisfy the written description required under 35 U.S.C. §112, first paragraph and respectfully request reconsideration and withdrawal of this rejection with respect to claim 148.

Conclusion

Applicants respectfully request that the above-made amendments and remarks be entered and made of record in the file history of the instant application. If there are any fees due in connection with the filing of this paper, please charge the fees to our deposit Account No. 08-3425. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account

Respectfully submitted,

Date: March 5, 2002

Janet M. Martineau (Reg. No. 46,903)

Human Genome Sciences, Inc.
9410 Key West Avenue
Rockville, MD 20850
(301) 315-2723 (telephone)

KKH/JMM

Telecopier Transmission Certificate

Send date 03/05/2002

I hereby certify that this paper and the attachments hereto are being sent by telecopier transmission to **703-746-5177** on the above-indicated date addressed to:

Examiner J. Seharaseyon - Group 1647
U.S. Patent and Trademark Office
Washington, D.C. 20231

Robyn Roberts 3/5/02
Robyn Roberts Date

Version To Show Changes Made

In the Claims:

Claims 56, 85, 86, 94-135 have been canceled without prejudice or disclaimer.

Please amend the following claims:

50. (Once Amended) A composition comprising the protein of claim 41 and a [pharmaceutically] acceptable carrier.

53. (Once Amended) An isolated protein comprising a polypeptide having an amino acid sequence selected from the group consisting of:

(a) the amino acid sequence of the full-length polypeptide encoded by the cDNA contained in ATCC Deposit No. 203500; and

(b) the amino acid sequence of the full-length polypeptide encoded by the cDNA contained in ATCC Deposit No. 203500 excluding the N-terminal methionine residue[; and

(c) the amino acid sequence of the mature polypeptide encoded by the cDNA contained in ATCC Deposit No. 203500].

61. (Once Amended) A composition comprising the protein of claim 53 and a [pharmaceutically] acceptable carrier.

64. (Once Amended) An isolated protein possessing anti-viral activity, comprising a polypeptide having an amino acid sequence at least 90% or more identical to an amino acid sequence selected from the group consisting of:

(a) amino acids 1 to 207 of SEQ ID NO:2;

(b) amino acids 7 to 207 of SEQ ID NO:2;

(c) amino acids 2 to 207 of SEQ ID NO:2; and

(d) amino acids 28 to 207 of SEQ ID NO:2.

77. (Once Amended) A composition comprising the protein of claim 64 and a [pharmaceutically] acceptable carrier.

80. (Once Amended) An isolated protein possessing anti-viral activity, comprising a polypeptide having an amino acid sequence at least 90% or more identical to an amino acid sequence selected from the group consisting of:

(a) the amino acid sequence of the full-length polypeptide encoded by the cDNA contained in ATCC Deposit No. 203500; and

(b) the amino acid sequence of the full-length polypeptide encoded by the cDNA contained in ATCC Deposit No. 203500 excluding the N-terminal methionine residue[; and

(c) the amino acid sequence of the mature polypeptide encoded by the cDNA contained in ATCC Deposit No. 203500].

91. (Once Amended) A composition comprising the protein of claim 80 and a [pharmaceutically] acceptable carrier.

145. (Once Amended) A composition comprising the protein of claim 136 and a [pharmaceutically] acceptable carrier.

157. (Once Amended) A composition comprising the protein of claim 148 and a [pharmaceutically] acceptable carrier.

160. (Once Amended) An isolated protein [comprising] consisting of at least 30 contiguous amino acid residues of SEQ ID NO:2.

161. (Once Amended) The isolated protein of claim 160, wherein the isolated protein [comprises] consists of at least 50 contiguous amino acid residues of SEQ ID NO:2.

166. (Once Amended) A composition comprising the protein of claim 160 and a [pharmaceutically] acceptable carrier.

169 (Once Amended) An isolated protein [comprising] consisting of at least 30 contiguous amino acid residues of the full-length polypeptide encoded by the cDNA contained in ATCC Deposit No. 203500.

170. (Once Amended) The isolated protein of claim 169, wherein the isolated protein [comprises] consists of at least 50 contiguous amino acid residues of the full-length polypeptide encoded by the cDNA contained in ATCC Deposit No. 203500.

175. (Once Amended) A composition comprising the protein of claim 169 and a [pharmaceutically] acceptable carrier.